UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen - ASD-ADHD Products Liability Litigation	:	22md3043 (DLC) 22mc3043 (DLC) 22cv8830 (DLC)
This Document Relates To: Chapman et al. v. Walmart, Inc. et al., 22cv8830	:	OPINION AND ORDER

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DENISE COTE, District Judge:

This Opinion addresses a portion of a motion to dismiss brought against one of the lawsuits in this multidistrict products liability litigation ("MDL"). Cherise Chapman, individually and on behalf of her minor child D.C. (together, "Plaintiffs"), has sued Johnson & Johnson Consumer Inc. ("JJCI") and Walmart, Inc. ("Walmart"; collectively, "Defendants"), alleging that her child has autism spectrum disorder ("ASD") and attention-deficit/hyperactivity disorder ("ADHD") because Chapman used the Defendants' acetaminophen products while pregnant. The Plaintiffs allege that the Defendants violated the law of Nevada when they failed to adequately warn of the risks of prenatal exposure to acetaminophen. For the following reasons, JJCI's motion to dismiss the Chapman complaint on the ground that it fails to plausibly plead either causation or JJCI's knowledge of the risk of developing ASD or ADHD is denied.

Background

The following facts are drawn from the Plaintiffs' short form complaint ("SFC") and the master complaint in this MDL that the SFC incorporates by reference. The facts are taken as true for the purposes of this motion.

Chapman resides in Nevada. While pregnant, Chapman took Tylenol Extra Strength ("Tylenol"). Chapman's child was born in

2015 and has ASD and ADHD. Chapman asserts that, had she been warned about the risk of ASD and ADHD, she would have taken less Tylenol or not taken it at all.

JJCI manufactures Tylenol. Acetaminophen has long been marketed as the only safe over-the-counter ("OTC") pain reliever for pregnant women. At the time Chapman took Tylenol, the label contained one warning related to pregnancy: "**If pregnant or breast-feeding**, ask a health professional before use." (Emphasis in original.) There was no specific warning about the risk of ASD or ADHD.

Several scientific studies have found prenatal exposure to acetaminophen to be associated with ASD and ADHD in children. The first cited study is from 2013. More studies followed.

On September 23, 2021, a group of 91 scientists, clinicians, and public health professionals published a "Consensus Statement." Ann Z. Bauer et al., Paracetamol Use During Pregnancy -- A Call for Precautionary Action, 17 Nature Revs. Endocrinology 757 (2021). In the Consensus Statement, the authors note:

> A growing body of experimental and epidemiological research suggests that prenatal exposure to paracetamol (N-acetyl-p-aminophenol (APAP), otherwise known as acetaminophen) might alter fetal development, which could in turn increase the risks of certain neurodevelopmental, reproductive and urogenital disorders. . . . [W]e believe we know enough to be concerned about the potential developmental risks

> associated with prenatal APAP exposure and therefore call for precautionary action.

Id. at 758-59. Among the "adverse neurodevelopmental outcomes" the Consensus Statement identifies are ASD and ADHD. Id. at 762. The signatories conclude:

> [W]e believe the combined weight of animal and human scientific evidence is strong enough for pregnant women to be cautioned by health professionals against its indiscriminate use, both as a single ingredient and in combination with other medications. We recommend that APAP should be used by pregnant women cautiously at the lowest effective dose for the shortest possible time. Long-term or high-dose use should be limited to indications as advised by a health professional. Packaging should include warning labels including these recommendations.

Id. at 764.

On June 7, 2022, the Plaintiffs filed this action in the U.S. District Court for the District of Nevada. On October 5, the Judicial Panel on Multidistrict Litigation consolidated this action with others asserting claims that prenatal exposure to acetaminophen causes ASD and ADHD in children and transferred the cases to this Court under 28 U.S.C. § 1407. On November 14, motions to dismiss two actions within the MDL on the ground of preemption were denied. In re Acetaminophen - ASD-ADHD Products Liability Litigation, No. 22md3043 (DLC), 2022 WL 17348351 (S.D.N.Y. Nov. 14, 2022) ("November Opinion").

At the November 17 initial pretrial conference, a schedule was set for the filing of two master complaints: one naming JJCI

and the other naming retailer defendants. On December 16, the MDL plaintiffs filed the master complaint against JJCI.

On January 20, 2023, Chapman filed her SFC, and on February 3, timely amended it. The SFC asserts Nevada state law claims against JJCI, to wit, claims for strict liability for failure to warn, strict liability for design defect due to inadequate warnings and precautions, negligence, negligent misrepresentation, breach of implied warranty, and violation of Nevada's consumer protection laws.[1]

On February 10, JJCI moved to dismiss all of the SFCs filed against it, including Chapman's.[2] The motion became fully submitted on March 17. On April 20, 2023, JJCI's motion to dismiss this action on the ground of preemption was denied. In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3026412 (S.D.N.Y. Apr. 20, 2023). This Opinion

[1] The Plaintiffs also assert a strict liability misrepresentation claim under the laws of states in which the Plaintiffs do not reside, including California. The SFC does assert, however, in its claim against Walmart, that Chapman purchased Walmart's store-branded acetaminophen in Sacramento, California.

[2] The Court has advised counsel that motions to dismiss should be brought against particular complaints and not against the master complaint. The master complaint is not the operative pleading; it is an administrative document. See Bell v. Publix Super Markets, Inc., 982 F.3d 468, 490 (7th Cir. 2020). JJCI's motion has been styled as brought against all complaints filed in the MDL. The Court, therefore, has chosen the Chapman SFC for this Opinion because it asserts claims against both JJCI and a Retailer Defendant and alleges that the acetaminophen taken by Chapman caused her child to develop both ASD and ADHD.

resolves that portion of the motion addressed to the adequacy of the pleading of the elements of causation and knowledge. The remaining ground for dismissal on which JJCI relies -- that the fraud-based claims are not adequately pled -- will be addressed in a separate Opinion.

Retailer Defendants, including Walmart, have also moved to dismiss all the SFCs filed against them. Separate Opinions have and will address those motions. See In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3045802 (S.D.N.Y. Apr. 21, 2023).

Discussion

JJCI asserts the Plaintiffs have not sufficiently pled causation or knowledge pursuant to Rule 8, Fed. R. Civ. P. "[I]n order to satisfy Federal Rule of Civil Procedure 8, a complaint must contain 'enough facts to state a claim to relief that is plausible on its face.'" Palin v. N.Y. Times Co., 940 F.3d 804, 810 (2d Cir. 2019) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Charles v. Orange County, 925 F.3d 73, 81 (2d Cir. 2019) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). "To stave off threshold dismissal for want of an adequate statement of their claim,

plaintiffs are required to do no more than state simply, concisely, and directly events that, they allege, entitle them to damages." Quinones v. City of Binghamton, 997 F.3d 461, 468 (2d Cir. 2021) (citation omitted).

Central to the Chapman's state law claims is her assertion that prenatal exposure to acetaminophen caused her child to develop ASD and ADHD. A multidistrict litigation transferee court "applies the substantive state law, including choice-of-law rules, of the jurisdiction in which the action was filed." Desiano v. Warner-Lambert & Co., 467 F.3d 85, 91 (2d Cir. 2006) (citation omitted). For the reasons explained in a recent Opinion, the substantive law of Nevada applies to this action. In re Acetaminophen - ASD-ADHD Prods. Liab. Litigation, 2022 WL 17348351, at *2.

Under Nevada law, a failure to warn claim consists of the following elements: "(1) the product had a defect which rendered it unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer, and (3) the defect caused the plaintiffs injury." Motor Coach Indus., Inc. v. Khiabani by and through Rigaud, 493 P.3d 1007, 1011 (Nev. 2021) (citation omitted). "[T]he lack of a warning functions as the relevant [product] defect." Id. (citation omitted). The Nevada Supreme Court has acknowledged that to establish liability for failure to warn claims, the defendant must have "knowledge, or by the

application of reasonable, developed human skill and foresight[,] should have knowledge of the danger." Allison v. Merck & Co., Inc., 878 P.2d 948, n.12 (Nev. 1994) (quoting Restatement (Second) of Torts § 402A cmt. j (Am. L. Inst. 1965)); see also Restatement (Third) of Torts: Products Liability § 2 cmt. m (Am. L. Inst. 1998) (noting that, in failure to warn cases about drugs, a "plaintiff should bear the burden of establishing that the risk in question was known or should have been known to the relevant manufacturing community").

1. Causation

JJCI contends that the complaint fails to plausibly plead causation since the scientific studies on which it relies suggest at most "an association" between the exposure to acetaminophen and the identified injuries of ASD and ADHD. It points out that not one of the studies identified in the complaint "affirmatively" finds that use of acetaminophen causes the two conditions.

The complaint gives fair notice to the Defendants of the theory of causation for the Nevada claims. By itself, the Consensus Statement provides a more than adequate pleading of the element of causation. A complaint is not the vehicle for presenting an expert's analysis of causation. The parties are currently engaged in discovery on the issue of general causation

and will be exchanging expert reports addressed to that topic over the next few months. They will be briefing Daubert motions in the Fall. JJCI's motion to dismiss for failure to plead causation is denied.

2. Knowledge

In a related argument, JJCI contends that the complaint does not plead a plausible inference that JJCI knew or should have known that use of acetaminophen during pregnancy causes ASD or ADHD. In making this argument, JJCI refers again to the individual studies identified in the complaint, and in particular to their caution against inferring a causal relationship based on the evidence described in a single study.[3]

The Nevada complaint adequately pleads that JJCI knew or should have known that there was a risk of ASD and ADHD from exposure in utero to Tylenol. It describes studies regarding the linkage between the use of acetaminophen and those two conditions and the reasons to believe that JJCI was aware of those studies. It is undisputed that, as the manufacturer of

[3] The JJCI motion also argues that the complaint's allegations regarding knowledge are especially deficient prior to the publication of the Consensus Statement in 2021 and entirely inadequate for the period before 2013. A motion to dismiss is not generally an appropriate vehicle to explore the strength of scientific evidence, much less its strength at any one point in time. Chapman's duty in crafting her complaint was to meet the requirements of Rule 8 for those claims governed by Rule 8. She had no duty to plead either causation or knowledge as of, for instance, a period of time before 2013.

Tylenol, JJCI had a responsibility to ensure that its label contained adequate warnings regarding use of the drug. See Wyeth v. Levine, 555 U.S. 555, 570-71 (2009). The complaint's allegations are sufficient to meet the Plaintiffs' burden under Rule 8 to plead knowledge.

Conclusion

JJCI's February 10, 2023 motion to dismiss the Chapman action for failure to plead causation and knowledge as required by Rule 8 is denied.

Dated: New York, New York
April 27, 2023

DENISE COTE
United States District Judge